

REMARKS

Applicants respectfully request reconsideration and allowance of the claims, in light of the remarks made herein.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 9, 10, 12, 13 and 25 are pending in this application. Claims 9, 10 and 25 are amended. Most of the amendments have been made simply to address formal matters, and are in accordance with a telephone conference between Applicants' representative and the Examiner on December 11, 2003, during which the Examiner indicated that the claims were in condition for allowance. Support for the amendments to claim 25 can be found on page 15, lines 9-14, of the specification. No new matter is added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art, and that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

II. THE REJECTIONS UNDER §112, 1ST PARAGRAPH, ARE OVERCOME

Claims 9, 10, 12, 13 and 25 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. The rejection is traversed.

The first aspect of this rejection is based on the assertion on page 2 of the Office Action that "Claim 9 is drawn to serine protease inhibitor fragments." This is incorrect. Part (a) of claim 9 requires that the polypeptide have a molecular weight of about 55 kilodaltons. This is clearly not a protein fragment, but is the molecular weight of the isolated protein, pernin, as inferred from the nucleotide sequence of the invention. (See page 6, lines 27-28 of the specification.)

The Office Action goes on to allege that "[t]he peptides of SEQ ID NO:1-5 are generated by chemical and enzymatic cleavage and therefore [are] not representative of fragments having full activity" and that "many structurally unrelated DNA are encompassed within the scope of these claims". These statements are also incorrect. The protein of claim 9 (not fragment, as

discussed above) must have full activity, as is required by part (b) of claim 9. Furthermore, claim 9 does not encompass structurally unrelated molecules, as they all comprise SEQ ID NO:1. As is discussed on page 17, lines 26-37, SEQ ID NO:1 is homologous to an anti-thrombin protein sequence from leeches, indicating that this portion of the permin protein is responsible for its serine protease inhibitor activity. Therefore, the protein to which claim 9 is directed is defined structurally, by molecular mass and by a portion of its sequence, and functionally, by its enzymatic properties. There is a correlation between structure and function, in that SEQ ID NO:1 is the portion of the protein that confers its enzymatic activity. Thus, written description clearly exists for claim 9.

The Office Action asserts, on page 3, that claim 10 is drawn to variants of SEQ ID NO:7, with an insufficient limitation on structure and derived from any source. The recitation "or a functionally equivalent variant of the polypeptide" has been removed from claim 10, obviating that portion of the rejection. With respect to the source of the protein, Applicants submit that they have taught how to isolate and characterize it from *P. canaliculus*, and that there is no reason to expect that an analog of SEQ ID NO:7 could not be isolated from other sources as well. Therefore, claim 10 should not be limited to a particular species, and is believed to be adequately described by the application.

The Office Action alleges that claim 25 does not contain sufficient structural limitation. It is believed that the current amendments to claim 25 address this issue. As is discussed on page 15, the 75 kilodalton band isolated from the recited process has a high degree of purity. Accordingly, it is submitted that claim 25 is a proper product-by-process claim (see MPEP §2173.05(p)I), and is therefore allowable.

Claims 9, 10, 12 and 13 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The rejection is traversed.

As discussed above, fragments of SEQ ID NO:7 are not contemplated by the claims, nor are the claims directed to proteins "with unlimited structure". Rather, there are specific limitations in each claim that enable the skilled artisan to make and use the invention with no undue experimentation. For instance, claim 9 requires a particular molecular mass and partial sequence of the polypeptide encoded by the claimed polynucleotide. Claim 10 requires a specific sequence, or a molecule that is complementary to a polynucleotide that hybridizes under stringent conditions to a polynucleotide of specific sequence. Claim 25 requires that the

polypeptide have a particular molecular mass, and that it is obtainable by a recited process that yields a substantially pure protein. Therefore, one of ordinary skill in the art, following the teachings of the application, would require no further guidance to arrive at the claimed invention.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, are requested.

III. THE REJECTIONS UNDER §112, 2ND PARAGRAPH, ARE OVERCOME

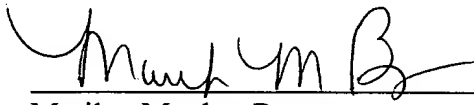
Claims 10, 12 and 13 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Office Action states that “a polynucleotide that hybridizes to the polynucleotide encoding SEQ ID NO:7 cannot encode a polypeptide having serine protease inhibiting activity.” Claim 10 has been amended to clarify that it is the complement of such a polynucleotide that is intended to be claimed. The Examiner is thanked for her assistance in clarifying this issue. Reconsideration and withdrawal of the indefiniteness rejection are requested.

CONCLUSION

In view of the remarks and amendments herewith, it is believed that the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicant



By: Marilyn Matthes Brogan
Reg. No. 31,223

Anne-Marie C. Yvon, Ph.D.
Reg. No. 52,390
Tel: (212) 588-0800